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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,614	07/19/2007	Jan Cornelis De Jong	U 016907-4	4798

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
03/11/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

nyuspatactions@ladas.com

Office Action Summary	Application No.	Applicant(s)	
	10/579,614	DE JONG ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,15,16,20-34,41-47 and 49-57* is/are pending in the application.

4a) Of the above claim(s) *1-12,15,16,20-34 and 41-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47 and 49-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 May 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and remarks filed December 21, 2009 are acknowledged and entered. Claims 1-12, 15, 16, 20-34, 41-47 and 49-57 are pending. Claims 1-12, 15, 16, 20-34 and 41-46 are withdrawn consideration being drawn to non-elected subject matter. Claims 47 and 49-57 are under examination.

2. The following objection/rejections are withdrawn:

- The objection to claims 47 and 49-55 because they recite the acronym, "EMCR-CoV" without explaining (either in the claims or the specification) how the letters of the acronym correspond to its meaning, is withdrawn in view of Applicant's remarks filed December 21, 2009. "EMCR-CoV" is the virus' name.
- The rejection of claims 47-55 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description (*i.e.*, new matter) requirement, is withdrawn in view of Applicant's amendment.

Drawings

3. The drawings are objected to because they do not recite sequence identifiers for each sequence. In lieu of amending the drawings, Applicant may amend the specification to include the identifiers in the "Brief Description of the Drawings" section. Correction is required. **Note that this objection will not be held in abeyance, see 37 CFR 1.85(a).**

Oath/Declaration

4. The oath or declaration remains defective for reasons of record. Applicant requests that this objection to the oath/declaration be held in abeyance.

Claims Summary

5. The claims are drawn to a method for determining whether a viral isolate is an EMCR-CoV virus. The method comprises the step of detecting whether the viral isolate more closely phylogenetically corresponds to SEQ ID NO: 1 or a functional fragment thereof compared to a viral isolate from a different coronavirus selected from the group consisting of PEDV, HCoV-229E, PRCoV, TGEV, CaCoV and FcCoV. More specifically, the sample is contacted with a nucleic acid primer or probe that is specific for the EMCR-CoV virus (or functional fragment thereof) that would only cause a reaction if and only if EMCR-CoV is present in the sample. The primer or probe has at 65% or at least 85% complementarity to RNA of EMCR-CoV or the functional fragment thereof. The functional fragment that may be detected in the method comprises an open reading frame that encodes EMCR-CoV replicase, nuclear capsid, matrix or spike protein.

The sample is from a mammal, specifically a human with atypical pneumonia. Identification of EMCR-CoV leads to a diagnosis of EMCR-CoV infection.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(*New Rejection*) Claims 47 and 49-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claims 47 and 55-57, the step of detecting whether a viral isolate more closely phylogenetically corresponds to SEQ ID NO: 1 than other viruses is not an active step. The claims do not recite any additional active method steps, but simply state a characterization or conclusion of the results of those steps or may be performed entirely in the human mind. While all of the technical details of a method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practiced. The minimum requirements for method steps minimally include a contacting step in which the reaction of the sample with the reagents necessary for the assay is recited, a detection step in which the reaction steps are quantified or visualized, and a correlation step describing how the results of the assay allow for the determination.

With regard to claims 49-57, the claims lack antecedent basis in claim 47 for the term "the sample".

It is noted that claim 56 refers to a diagnosis step "based on the identifying" in claim 55, however, claim 55 does not reference an identifying step, nor does claim 1. Therefore, there is a lack of antecedent basis for the subject matter of claim 56.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 51 and 52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of primers and probes that are specific to EMCR-CoV, does not reasonably provide enablement for primers and probes that have at least 65% or

80% complementarity to RNA of the EMCR-CoV virus or a functional fragment thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Applicant's arguments have been carefully considered but fail to persuade. Applicant argues that claims 51 and 52 are limited to primers and probes that have the recited degree of complementarity and that are specific to EMCR-CoV (as recited in claim 47). Applicant argues that since claims 51 and 52 are narrower than claim 47, there is no basis for a scope of enablement rejection.

In response to Applicant's arguments, there is a basis for the scope of enablement rejection as set forth above. Applicant has identified a probe or primer that can distinguish from other viruses: SEQ ID NO: 1. Claims 51 and 52 encompass a sequence that is not identical to SEQ ID NO: 1 that can specifically detect EMCR-CoV. Such a sequence has not been identified by Applicant, and it is not clear how to construct a sequence that is not identical to SEQ ID NO: 1 yet retains the ability to bind only to EMCR-CoV. It is recognized that the claim indicates that the sequences are capable of binding only to EMCR-CoV, however, the specification must enable one to make and use those sequences. Therefore, the rejection is maintained for reasons of record.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47 and 49-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. (Claim 47 is newly rejected here in view of Applicant's amendment to the claim.)

The methods claimed in claims 47 and all dependent claims comprise the identification of a viral isolate that "more closely phylogenetically corresponds to SEQ ID NO: 1 or a functional fragment than it does to a viral isolate from a different coronavirus". The phrase "more closely phylogenetically corresponds" is relative and lacks comparative basis. Applicant has not identified which parameters qualify as determinants of whether the isolate more closely phylogenetically corresponds to SEQ ID NO: 1 than it does to a different coronavirus.

Applicant argues that the art is such that those of ordinary skill could be relied upon to determine with a reasonable degree of particularity whether a particular viral isolate is more closely identifiable phylogenetically to one particular genus of virus than another. Applicant points to US Patent 7,531,342, claim 1, as an example. The Office has considered Applicant's arguments, but they are not found persuasive. In response, each case is decided on its own merits. Even so, the patented claim defines "phylogenetically corresponding" as being 90% identical to a particular sequence. The instant claims, with the exception of claims 51 and 52, do not require any particular degree of identity to determine whether the viral isolate falls within the metes and bounds of being more closely phylogenetically corresponding to SEQ ID NO: 1 or a functional fragment thereof. With regard to claims 51 and 52 which do recite at least 65% and 80% complementarity to RNA of the EMCR-CoV virus or a functional fragment thereof, there is no sequence given with which to compare, unless Applicant intends the comparison of 65% and 80% to be done with SEQ ID NO: 1, in which case this should be made more clear in the claims.

Further, with regard to claims 47 and 49-57, a "functional fragment" of SEQ ID NO: 1 has not been defined in terms of its function. While fragments of SEQ ID NO: 1 can be determined, fragments that are "functional" cannot be determined without knowing the function that the fragment must possess. Applicant argues that the teachings of the prior art are such that one of ordinary skill in the art could be relied upon to determine whether a fragment of a particular viral isolate is functional or not. In response to Applicant's argument, it may be possible to determine whether a fragment is functional if Applicant identifies the function. As it stands, the claims only refer to a functional fragment of the virus without saying what function the fragment is capable of.

Conclusion

9. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B Chen/

Primary Examiner, Art Unit 1648